

**REMARKS**

The pending Office Action addresses and rejects claims 1-26 and 29-63. Applicants respectfully request reconsideration and allowance based on the remarks submitted herewith.

***Rejections Pursuant to 35 U.S.C. § 103(a)***

***U.S. Patent No. 5,209,753 of Biedermann et al. in view of U.S. Patent No. 5,122,132 of Bremer***

The Examiner reject claims 1-7, 12, 13, 15, 16-22, 29-35, 40-46, and 48-55 pursuant to 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,209,753 of Biedermann et al. ("Biedermann") in view of U.S. Patent No. 5,122,132 of Bremer ("Bremer"). The Examiner argues that Biedermann discloses an apparatus for attaching tissue to bone as claimed by Applicants except for the distal tip member being of a harder material than a proximal main member. The Examiner relies on Bremer to remedy the deficiencies of Biedermann. Applicants disagree.

***Claims 1-7, 12, 13, 15, and 16-22***

Claim 1 is directed to an apparatus for attaching tissue to bone that includes an expandable body made of both a proximal main member and a distal tip member, an expander pin that expands the expandable body laterally when the expander pin is driven into the expandable body, and a tissue attachment member formed on a shaft of the expander pin. More particularly, when the expander pin is driven into the expandable body, the expandable body is attached to the bone and the tissue attachment member secures tissue to the apparatus. When the expandable body is expanded, both the proximal main member and the distal tip member expand because both are components of the expandable body.

Biedermann is directed to a bone screw that is used as a pedicle screw. (See Col. 1, lines 4-6.) The bone screw (1) includes an intermediate threaded portion (2) that can be expanded by first engaging a shaft of an expander pin (16) located proximal of the intermediate expandable threaded portion (2) with an expander part (12) that is located distal of the intermediate expandable threaded

portion (2), and then unscrewing the expander pin (16) to move the expander part (12) in a proximal direction to expand the intermediate threaded portion (2). (See Col. 2, lines 19-29 and 34-45.) The Examiner asserts that the expander part (12) forms the claimed distal tip member, the expandable threaded portion (2) forms the claimed proximal main member, and the shaft of the expander pin (16) forms the claimed expander pin. While the Examiner admits Biedermann fails to teach the distal tip member (12) being formed of a harder material than the proximal main member (2), the Examiner has overlooked several additional deficiencies of Biedermann.

First, the claimed apparatus includes an expandable body having a distal tip member and a proximal main member, both of which are expandable because they are components of the expandable body. In the bone screw (1) of Biedermann, on the other hand, only the intermediate threaded portion (2) is expandable. The distal expander part (12) of the bone screw (1) of Biedermann is not expandable. Rather, it is configured to perform the expansion of the intermediate threaded portion (2). Accordingly, Biedermann fails to teach or even suggest both a distal tip member and a proximal main member that are expandable.

The claimed apparatus also requires that the proximal main member *of the expandable body* include a distally extending threaded projection that is threadably interengageable with a distally extending threaded recess in a proximal surface of the distal tip member of the expandable body. While the bone screw (1) of Biedermann does include a recess (13) formed in the distal expander part (12) that can be engaged by a threaded projection (18), the threaded projection (18) is not part of the intermediate expandable threaded portion (2) (i.e., the proximal main member); it is part of the shaft of the expander pin (16) used to engage the distal expander part (12) to expand the intermediate threaded portion (2). Accordingly, Biedermann further fails to teach a proximal main member having a distally extending threaded projection.

The claimed apparatus further includes a tissue attachment member that is formed on the shaft *of the expander pin*. Even though Biedermann is a bone screw that is particularly suited for use as a pedicle screw and thus would not be used by a person having ordinary skill in the art to

attach tissue to bone, the Examiner alleges that the head (3) of the bone screw (1) is the equivalent of Applicants' tissue attachment member (210). Even if the head (3) of the bone screw (1) could possibly be used to attach tissue to bone, the head (3) of the bone screw (1) is formed on the intermediate expandable threaded portion (2) (i.e., the proximal main member), not the shaft of the expander pin (16) as required by claim 1. In fact, a tissue attachment member would never be formed on the shaft of the expander pin (16) of Biedermann because the expander pin (16) is removed from the bone screw (1) once the implantation is complete. This is vastly different from the claimed apparatus, which maintains the expander pin (200), and thus the tissue attachment member (210), as part of the apparatus even after the implantation is complete. Accordingly, Biedermann fails to teach or even suggest a tissue attachment member that is formed on the shaft of the expander pin.

Claim 1 also requires that, "when said expander pin is driven into said expandable body, said expandable body is attached to the bone and said tissue attachment member secures the tissue to said apparatus." Biedermann fails to teach or even suggest a device that is capable of performing this function. As described above, when the shaft of the expander pin (16) of Biedermann is driven into the intermediate expandable threaded portion (2), it engages the distal expander part (12), however it does not expand the body (2) and attach the body (2) to the bone or secure the tissue to the apparatus. Expansion of the intermediate expandable threaded portion (2) only occurs in Biedermann when the shaft of the expander pin (16) is unscrewed to be *removed*, resulting in movement of the distal expander part (12) to expand the intermediate threaded portion (2). Further, as explained above, movement of the shaft of the expander pin (16), either driving it into or removing it from the intermediate expandable threaded portion (2), fails to secure any tissue to the bone screw (1). Thus, because the only way to expand any portion of the bone screw (1) in Biedermann is to remove the shaft of the expander pin (16), and because movement of the expander pin (16) into the intermediate expandable threaded portion (2) fails to secure the tissue to the apparatus, Biedermann fails to teach or even suggest the claimed apparatus.

Accordingly, Biedermann is deficient as a reference for numerous reasons. Bremer does not remedy the deficiencies of Biedermann. Bremer, which the Examiner relies upon to teach an apparatus where a distal portion is made from a harder material than a proximal main portion, does not include any expandable body or expander pin. In fact, Bremer is not even configured to expand. Bremer is merely relied on to teach material properties.

Claim 1, as well as claims 2-7, 12, 13, 15, and 16-22 which depend therefrom, therefore represents allowable subject matter.

*Claims 29-35, 40-46, and 48-55*

Claim 29 is directed to an apparatus for attaching tissue to bone that includes an expandable body, an expander pin that expands the expandable body laterally when the expander pin is driven into the expandable body, and a tissue attachment member formed on a shaft of the expander pin. More particularly, when the expander pin is driven into the expandable body, the expandable body is attached to the bone and the tissue attachment member secures tissue to the apparatus.

The only component of Biedermann that expands the expandable body (2) is the expander part (12). The expander pin (16) is used to move the expander part (12), but it does not expand the expandable body (2). Nevertheless, even if the expander pin (16) is considered to be a component that expands the expandable body (2), neither it nor the expander part (12) includes anything that can be considered to be a tissue attachment member. Bremer, fails to remedy any of the deficiencies of Biedermann, as previously explained.

Claim 29, as well as claims 30-35, 40-46, and 48-55, therefore represents allowable subject matter.

U.S. Patent No. 5,209,753 of Biedermann et al. in view of U.S. Patent No. 5,122,132 of Bremer further in view of any one of U.S. Patent No. 5,370,662 of Stone et al., U.S. Patent No. 5,948,002 of Bonutti, U.S. Patent No. 5,725,529 of Nicholson, and U.S. Patent No. 5,078,818 of Moll et al.

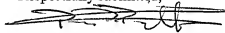
The Examiner makes a number of further obviousness rejections pursuant to 35 U.S.C. § 103(a), relying on Biedermann, Bremer, and one of a number of different references. More particularly, the Examiner further relies on U.S. Patent No. 5,370,662 of Stone et al. to reject claims 8-10 and 36-38, U.S. Patent No. 5,948,002 of Bonutti to reject claims 11 and 39, U.S. Patent No. 5,725,529 of Nicholson to reject claims 14 and 47, and U.S. Patent No. 5,078,818 of Moll et al. to reject claims 23-26 and 56-59. None of the references cited by the Examiner remedy the deficiencies of Biedermann. Accordingly, at least because claims 8-11, 14, 23-26, 36-39, 47, and 56-59 depend from allowable base claims, each claim also represents allowable subject matter.

### **Conclusion**

All pending claims are believed to be in condition for allowance. If the Examiner believes that an interview would facilitate the resolution of any outstanding issues, he is kindly requested to contact the undersigned.

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Respectfully submitted,



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**PENDING CLAIMS**

1. (Previously Presented) Apparatus for attaching tissue to bone comprising:  
an expandable body defining a bore and configured to expand into bone, said expandable body comprising a distal tip member and a proximal main member, said distal tip member being of harder material than said proximal main member, said distal tip member having a threaded recess in a proximal surface thereof and said proximal main member having a distally extending threaded recess in a proximal surface thereof and said proximal main member having a distally extending threaded projection threadably interengageable with the distal tip member recess;  
an expander pin comprising a shaft sized to be received in the bore of said expandable body and expand said expandable body laterally when said expander pin is driven into said expandable body; and  
a tissue attachment member formed on said shaft;  
whereby when said expander pin is driven into said expandable body, said expandable body is attached to the bone and said tissue attachment member secures the tissue to said apparatus.
2. (Previously Presented) Apparatus according to claim 1 wherein said expander pin includes a fastener stabilization apparatus for stabilizing said expander pin relative to said expandable body.
3. (Original) Apparatus according to claim 2 wherein said fastener stabilization apparatus comprises threads.
4. (Original) Apparatus according to claim 2 wherein said fastener stabilization apparatus comprises ribs.
5. (Previously Presented) Apparatus according to claim 1 wherein said tissue attachment member comprises at least one laterally-extending projection for tacking tissue.
6. (Original) Apparatus according to claim 5 wherein said at least one laterally-extending projection has as substantially linear outer edge.

7. (Original) Apparatus according to claim 5 wherein said at least one laterally-extending projection has a substantially arc-like outer edge.
8. (Previously Presented) Apparatus according to claim 1 wherein said tissue attachment member comprises a bore formed in said expander pin and a suture extending through said expander pin bore.
9. (Previously Presented) Apparatus according to claim 8 wherein said tissue attachment member is configured so that said suture may slide relative to said expander pin when said expander pin is received in said expandable body.
10. (Previously Presented) Apparatus according to claim 8 wherein said tissue attachment member further comprises a second bore formed in said expander pin and second suture extending through said second expander pin bore.
11. (Original) Apparatus according to claim 1 wherein said expander pin has indicia for indicating depth.
12. (Previously Presented) Apparatus according to claim 1 wherein said expandable body distal tip member is tapered.
13. (Previously Presented) Apparatus according to claim 1 wherein said expandable body includes a bone securement apparatus for securing said expandable body relative to bone.
14. (Original) Apparatus according to claim 13 wherein said bone securement apparatus comprises ribs.
15. (Original) Apparatus according to claim 13 wherein said bone securement apparatus comprises threads.

16. (Original) Apparatus according to claim 1 wherein said apparatus further comprises an installation tool, and wherein said installation tool comprises a shaft sized to be slidably received in said bore of said expandable body and in a bore of said expander pin.
17. (Original) Apparatus according to claim 16 wherein said shaft is releasably attachable to said expandable body.
18. (Original) Apparatus according to claim 16 wherein said shaft and said expandable body are threadably interengageable with one another.
19. (Original) Apparatus according to claim 16 wherein said shaft has a tapered distal end.
20. (Original) Apparatus according to claim 16 wherein said shaft extends distally beyond said expandable body when said shaft is slidably received in said bore of said expandable body.
21. (Original) Apparatus according to claim 16 wherein said apparatus further comprises a pusher member configured to drive said expander pin into said expandable body.
22. (Original) Apparatus according to claim 21 wherein said pusher member slides along said shaft when driving said expander pin into said expandable body.
23. (Original) Apparatus according to claim 1 wherein said apparatus further comprises a cannulated driver assembly adapted to drive said expander pin into said expandable body.
24. (Original) Apparatus according to claim 23 wherein said cannulated driver assembly slides along a shaft connected to said expandable body.
25. (Original) Apparatus according to claim 23 wherein said cannulated driver assembly includes a trigger for inducing the driving of said expander pin.
26. (Original) Apparatus according to claim 23 wherein said cannulated driver assembly comprises a slap hammer.



27. (Cancelled).
28. (Cancelled).
29. (Previously Presented) Apparatus for attaching tissue to bone comprising:  
an expandable body configured to expand into bone, said expandable body defining a bore;  
an expander pin comprising a shaft sized to be received in the bore of said expandable body  
and expand said expandable body laterally when said expander pin is driven into said expandable  
body; and  
a tissue attachment member formed on said shaft;  
whereby when said expander pin is driven into said expandable body, said expandable body  
is attached to the bone and said tissue attachment member secures the tissue to said apparatus.
30. (Previously Presented) Apparatus according to claim 29 wherein said expander pin includes  
a fastener stabilization apparatus for stabilizing said expander pin relative to said expandable body.
31. (Original) Apparatus according to claim 30 wherein said fastener stabilization apparatus  
comprises threads.
32. (Original) Apparatus according to claim 30 wherein said fastener stabilization apparatus  
comprises ribs.
33. (Previously Presented) Apparatus according to claim 29 wherein said tissue attachment  
member comprises at least one laterally-extending projection for tacking tissue.
34. (Original) Apparatus according to claim 33 wherein said at least one laterally-extending  
projection has a substantially linear outer edge.
35. (Original) Apparatus according to claim 33 wherein said at least one laterally-extending  
projection has a substantially arc-like outer edge.

36. (Previously Presented) Apparatus according to claim 29 wherein said tissue attachment member comprises a bore formed in said expander pin and a suture extending through said bore formed in said expander pin.
37. (Previously Presented) Apparatus according to claim 36 wherein said tissue attachment member is configured so that said suture is slidable relative to said expander pin when said expander pin is received in said expandable body.
38. (Previously Presented) Apparatus according to claim 36 wherein said tissue attachment member further comprises a second bore formed in said expander pin and a second suture extending through said second expander pin bore.
39. (Original) Apparatus according to claim 29 wherein said expander pin has indicia for indicating depth.
40. (Original) Apparatus according to claim 29 wherein said expandable body is provided with a tapered distal end.
41. (Original) Apparatus according to claim 29 wherein said expandable body comprises a distal tip member and a proximal main member, said distal tip member being separable from said proximal main member.
42. (Original) Apparatus according to claim 41 wherein said distal tip member and said proximal main member are threadedly interengageable with one another.
43. (Original) Apparatus according to claim 41 wherein said distal tip member and said proximal main member are frictionally interengageable with one another.
44. (Original) Apparatus according to claim 29 wherein said expandable body comprises a distal tip member constructed from a first material and a proximal main member constructed from a second material, and wherein said first material is harder than said second material.

45. (Original) Apparatus according to claim 41 wherein said expandable body distal tip member is tapered.
46. (Previously Presented) Apparatus according to claim 29 wherein said expandable body includes a bone securement apparatus for securing said expandable body relative to bone.
47. (Original) Apparatus according to claim 46 wherein said bone securement apparatus comprises ribs.
48. (Original) Apparatus according to claim 46 wherein said bone securement apparatus comprises threads.
49. (Original) Apparatus according to claim 29 wherein said apparatus further comprises an installation tool, and wherein said installation tool comprises a shaft sized to be slidably received in said bore of said expandable body and a bore of said expander pin.
50. (Original) Apparatus according to claim 49 wherein said shaft is releasably attachable to said expandable body.
51. (Original) Apparatus according to claim 49 wherein said shaft and said expandable body are threadably interengageable with one another.
52. (Original) Apparatus according to claim 49 wherein said shaft is provided with a tapered distal end.
53. (Original) Apparatus according to claim 49 wherein said shaft extends distally beyond said expandable body when said shaft is slidably received in said bore of said expandable body.
54. (Original) Apparatus according to claim 49 wherein said apparatus further comprises a pusher member configured to drive said expander pin into said expandable body.

55. (Original) Apparatus according to claim 54 wherein said pusher member slides along said shaft when driving said expander pin into said expandable body.
56. (Original) Apparatus according to claim 29 wherein said apparatus further comprises a cannulated driver assembly adapted to drive said expander pin into said expandable body.
57. (Original) Apparatus according to claim 56 wherein said cannulated driver assembly slides along a shaft connected to said expandable body.
58. (Original) Apparatus according to claim 56 wherein said cannulated driver assembly includes a trigger for inducing the driving of said expander pin.
59. (Original) Apparatus according to claim 56 wherein said cannulated driver assembly comprises a slap hammer.
60. (Original) Apparatus according to claim 5 wherein said at least one laterally-extending projection has a substantially convex configuration.
61. (Original) Apparatus according to claim 5 wherein said at least one laterally-extending projection has a substantially planar configuration.
62. (Original) Apparatus according to claim 5 wherein said at least one laterally-extending projection has a substantially concave configuration.
63. (Previously Presented) Apparatus according to claim 5 wherein said tissue attachment member further comprises at least one longitudinally-extending projection projecting distally out of said at least one laterally-extending projection.